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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/500,713 02/09/00 CONNOR J 98-2046

HM22/0813

Thomas J Monahan
Intellectual Property Office
the Pennsylvania State University
113 Technology Center
University Park PA 16802

EXAMINER

CHERNYSHEV, O

ART UNIT

PAPER NUMBER

1646

10

DATE MAILED:

08/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/500,713

Applicant(s)

CONNOR ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 17-29 is/are pending in the application.
- 4a) Of the above claim(s) 26-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 17-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claim 1, 8 and 10 have been amended and claims 17-29 (corresponding 11-23, Rule 1.126) have been added as requested in the Response to Office action of Paper # 9, filed on May 21, 2001. Claims 1-10 and 17-29 are pending in the instant application.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 11-23 been renumbered 17-29.

2. Newly submitted claims 26-29 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 26-29 are drawn to a method for detection of demyelinating disease in sample using an antibody. The newly submitted invention is different from originally elected because these inventions are directed to different methods that recite structurally and functionally distinct elements, are not required one for the other, achieve different goals, and therefore constitute patentably distinct inventions.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 26-29 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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3. Claims 1-10 and 17-25 are under examination in the instant office action.
4. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action
5. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
6. Applicant's arguments filed on May 21, 2001 have been fully considered but they are not deemed to be persuasive.
7. Applicants argue that presented claims are definite and independent Claim 1 does not require a step, which indicates the detection of a demyelinating disease. The Examiner disagrees with this argument for the following reasons. The part c) of the Claim 1 states "measuring the extent of binding of said iron binding protein to said sample, under conditions such that a demyelinating disease is detected". It is not clear from the claim what is exactly meant by conditions for detection of demyelinating disease. If it is the lack of ferritin binding or differential binding, relative binding, degree of binding, binding index or any other definite criteria, then it should be indicated in the claim as a last step, which is predicative of demyelinating disease. Otherwise, the claim remains indefinite for omitting the final essential step of the claimed method.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: see the arguments regarding Claim 1 earlier in this office action.

Claims 2-10 and 18-25 are indefinite for being dependent from the indefinite claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for the detection of a demyelinating disease using samples of brain tissue, does not reasonably provide enablement for a method for the detection of a demyelinating disease using any other samples. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 1 and 17 are directed to a method for the detection of demyelinating disease, which involves using a sample from a human suspected of having a demyelinating disease. The claims are broad enough to encompass any sample, including, for example, fluid samples like blood, blood serum, blood plasma, cerebral spinal fluid, lymph or urine. However, the instant specification is not enabled for any sample except the samples of brain tissue. It would require undue experimentation for one skilled in the art to practice the invention as currently claimed using for example fluid samples, or any other samples of human tissue, except samples of the brain tissue.

The factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature

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of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. In re Wands, 8 USPQ2d, 1400 (CAFC 1988).a

As it is stated on page 3 of the instant specification "The present invention also contemplates a method of detection of demyelinating disease comprising providing a fluid sample from a human suspected of having a demyelinating disease, reacting said fluid sample with human ferritin binding protein, and detecting the binding of antibodies within said fluid sample to said ferritin binding protein" (lines 16-19, emphasis added by the Examiner). However, there is no guidance provided in the specification, which would teach one skilled in the art how exactly the claimed method is supposed to work with fluid samples. There is no detailed protocol or even one working example to support the claimed method for liquid samples. The instant specification provides detailed description of the method using samples of brain slices, and as a conclusion of the description on page 18 of the instant application it states that "[] these data serve as background for embodiments of the present invention which are directed to the detection of antibodies against brain ferritin binding protein in the brain as a diagnostic method for multiple sclerosis" (lines 22-24). Nevertheless, the state of the art of protein binding using antibodies or any other binding substances is not predictable enough to extrapolate the data collected from the experiments on tissue slices to predict the success of the same technique (method) when working with liquid samples.

In view of the lack of teachings and unpredictability of the art set forth earlier, and also the total absence of the working examples, the instant specification is not found to be enabling for a method for the detection of demyelinating disease, which involves using a sample from a

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human suspected of having a demyelinating disease, except the brain tissue sample. It would require undue experimentation and making a substantial inventive contribution for the skilled artisan to discover how to use Applicants' invention as currently claimed.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-0294 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

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Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. *OC*
August 8, 2001



JOHN ULM
PRIMARY EXAMINER
GROUP 1800